IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8964

Bartle, J. November 14, 2012

Patricia A. Spivack ("Ms. Spivack" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. John M. Spivack, Ms. Spivack's spouse, also has submitted a claim for derivative benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Carrie A. Totta, M.D. Based on an echocardiogram dated May 23, 2002, Dr. Totta attested in Part II of claimant's Green Form that Ms. Spivack suffered from moderate mitral regurgitation and an abnormal left atrial dimension.[4] Based on such findings,

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Dr. Totta also attested that Ms. Spivack had New York Heart Association Class II symptoms. This condition is not at issue in this claim.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of $522,266.[5]

In the report of claimant's echocardiogram, Dr. Totta stated, "There is left atrial enlargement; the left atrium measures 5.5 cm in the apical view, otherwise, the cardiac chamber sizes are within normal limits." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii).

In January, 2006, the Trust forwarded the claim for review by Robert A. Skotnicki, D.O., F.A.C.C., F.A.S.C.A.I., one of its auditing cardiologists. In audit, Dr. Skotnicki determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Spivack had an abnormal left atrial dimension. Dr. Skotnicki explained:

> The left atrial superior-inferior [sic] dimension is measured incorrectly by the sonographer. The sonographer initiates the measurement at the closure point of the mitral leaflets. It is correctly started at the mitral annulus. When performed correctly

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5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim.

> in the fashion, the left atrial superior-inferior [sic] dimension is only 5 cm. This is taken from the frame that planimeters the left atrial area that the sonographer utilized. Thus, it is not medically reasonable to state that the left atrial superior-inferior [sic] diameter is greater than 5 cm.

Based on the auditing cardiologist's finding that claimant did not have an abnormal left atrial dimension, the Trust issued a post-audit determination denying Ms. Spivack's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant submitted letters from Tom V. Pagano, M.D. and Michael S. Mancina, M.D., F.A.C.C., who agreed with the attesting physician that claimant had an abnormal left atrial dimension. Specifically, Dr. Pagano stated that claimant's left atrial dimension in the anterior long axis view was 5.4 cm. Dr. Mancina concluded that claimant's left atrial dimension was 5.38 cm. Based on these statements, claimant argued that the auditing cardiologist failed properly to apply the reasonable medical basis standard. In addition, claimant argued that there was a reasonable medical basis for the attesting physician's representation because the reports of

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Spivack's claim.

echocardiograms performed on August 4, 2003 and October 13, 2004 each note left atrial enlargement.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Skotnicki submitted a declaration in which he again concluded that there was no reasonable basis for the finding of an abnormal left atrial dimension.

The Trust then issued a final post-audit determination, again denying Ms. Spivack's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Spivack's claim should be paid. On November 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6696 (Nov. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 20, 2007, and claimant submitted a sur-reply on April 19, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[7] to review claims after the Trust and

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7. A "[Technical] [A]dvisor's role is to act as a sounding board (continued...)

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving by a preponderance of the evidence that there is a reasonable medical basis for the attesting physician's finding that she had an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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7. (...continued)
for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Spivack argues that she has established a reasonable medical basis for her claim because three different cardiologists independently agreed that she had an abnormal left atrial dimension. Claimant contends that the difference between the opinions provided by claimant's physicians and the auditing cardiologist, four-tenths of a centimeter, is explained by the concept of inter-reader variability. Finally, Ms. Spivack asserts that the auditing cardiologist failed to apply the reasonable medical basis standard because he simply substituted his judgment for that of the attesting physician.

In response, the Trust argues that claimant has failed to establish a reasonable medical basis for her claim. According to the Trust, the opinions of claimant's physicians do not rebut or refute Dr. Skotnicki's findings during audit that the left atrial was incorrectly measured. The Trust further asserts that inter-reader variability does not establish a reasonable medical basis for the claim because Dr. Skotnicki accounted for inter-reader variability and "this is clearly not a 'close call.'"

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension. Specifically, Dr. Vigilante found that:

> Visually, the left atrium appeared at the upper limits of normal in size. I digitized the cardiac cycles in the parasternal

> long-axis and apical four chamber views in which the left atrium appeared the largest. I measured the left atrium by electronic calipers.... I determined that the largest left atrium measurement in the supero-inferior dimension was 5.3 cm. This measurement was taken from the mitral annulus to the posterior left atrial wall. This measurement was perpendicular to the mitral annulus and I excluded pulmonary vein structures in this measurement.

The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See Settlement Agreement § IV.B.2.c.(2)(b)ii). Here, each of Ms. Spivack's cardiologists reviewed her echocardiogram and determined that it demonstrated an abnormal left atrial dimension. Specifically, Dr. Totta determined that claimant's echocardiogram demonstrated a left atrial dimension of 5.5 cm in the apical four chamber view, Dr. Pagano determined that it measured 5.4 in this view, and Dr. Mancina determined that it measured 5.38 in this view. Although Dr. Vigilante disagreed with the measurements these physicians obtained, he measured Ms. Spivack's left atrium to be exactly 5.3 cm in the apical four chamber view. Given the particular circumstances presented here, we conclude that claimant has met her burden of proving that there is a reasonable medical basis for finding that she had an abnormal left atrial dimension. Therefore, we will reverse the Trust's denial of

Ms. Spivack's claim for Matrix Benefits and the derivative claim submitted by her spouse.